HYGIA HEALTH SERVICES

APR - 8 2002

K012417
Page 1 of 3

510 (k) Summary

Summary

Substantial Equivalence Summary for the Hygia Health Services Reprocessed Kendall SCD™ Sleeves

In accordance with 21 CFR Part 807.92, this summary is submitted by:

Hygia Health Services
2800 Milan Court
Suite 259
Birmingham, Alabama 35211
Date: July 15, 2001

1. Contact Person

Geoff M. Fatzinger
Director, Compliance and Regulatory Affairs
(205) 943-6670

2. Name of the Device

Classification Name: Compressible Limb Sleeve
Common or Usual Name: Sequentially Compressible Limb Sleeve
Review Panel: Cardiovascular
Classification: Class II
Proprietary Name: Hygia Health Services Reprocessed Kendall SCD™ Sleeve

3. Predicate Device

Classification Name: Compressible Limb Sleeve
Common Name: Sequentially Compressible Limb Sleeve
Classification: Class II
Proprietary Name: Kendall SCD™ Sleeve

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4. Statement of Substantial Equivalence

The Hygia Health Services Reprocessed Kendall SCD™ Sleeve employs no new technology other than the method used to reprocess the sleeve in order to allow the device to be utilized more than once. The Hygia Health Services Reprocessed Kendall SCD™ Sleeve is substantially equivalent to the Kendall SCD™ Sleeve in that the basis of operation for both devices is the sequential inflation of expandable sleeves, which are placed around the patient's lower limbs. The sleeves are then connected to a controller via a series of plastic tubes. Inflation of the sleeves is accomplished using ambient air, and a controller cycle that functions to alternately inflate and deflate the sleeves in a predetermined manner and interval.

The Hygia Health Services Reprocessed Kendall SCD™ Sleeve is substantially equivalent in function, operating parameters, and intended use to the Kendall SCD™ Sleeve that is currently commercially available and in distribution. There is no significant change in the device other than the Hygia Health Services Reprocessed Sleeve has been reprocessed via thermal high-level disinfection (HLD) so as to make the sleeve able to be reused. The original Kendall SCD™ Sleeve is marked for single patient use only. The Hygia Health Services HLD reprocess protocol does not alter the device's efficacy, safety, composition, or intended use.

5. Description of the Device

The Hygia Health Services Reprocessed SCD™ Sleeve is a compression limb device that, when attached to an approved controller, provides intermittent, sequentially graduated pressure. As the sleeves compress the legs, veins collapse, forcing the blood to move upward towards the heart. After compression, the sleeves deflate which allows the veins to reopen and bring oxygenated blood to the region. The inflation and deflation sequence is predetermined by the controller, which inflates first the ankle section, then the calf section, and finally the thigh section (on larger models). The pressure of compression is determined by the controller and is adjusted by varying the ankle pressure.

6. Intended Use of the Device

The Hygia Health Services Reprocessed Kendall SCD™ Sleeve is designed to operate in the identical manner as the predicate device, the Kendall SCD™ Sleeve. It is designed to apply sequential compression to a patient's lower limbs for the treatment of edema and ulcers secondary to venous insufficiency and for the prevention of deep vein thrombosis (DVT). The device is intended to be used

in both the home and institutional settings on patient populations for which this device is applicable

7. Technological Characteristics

The technological characteristics of the Hygia Health Services Reprocessed Kendall SCD™ Sleeve are identical to the original Kendall SCD™ Sleeves in overall design, materials, energy source, mode of operation, and performance characteristics.

8. Performance Data

Nonclinical Tests- Comparative bench testing was utilized to assess and prove similarity of function between the Hygia Health Service Reprocessed Kendall SCD™ Sleeves and the original Kendall SCD™ Sleeve. All tests found that functional and operational performance characteristics including compression, pressure control, timing sequence, sleeve compatibility, safety and operational parameters used when connected to a controller where substantially equivalent.

Clinical Tests- Clinical test results were summarized in support of the premarket notification submission.

Test Conclusions- Clinical and nonclinical test results of the Hygia Health Services Reprocessed Kendall SCD™ Sleeves indicated substantial equivalence to the predicate Kendall SCD™ Sleeves in all respects.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 8 2002

Mr. Geoff M. Fatzinger, BS, MS
Director, Compliance/Regulatory Affairs
Hygia Health Services, Inc.
2800 Milan Court, Suite 259
Birmingham, AL 35211

Re: K012417
Trade Name: Hygia Health Services Reprocessed Kendall SCD™ Sleeves
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: February 7, 2002
Received: February 8, 2002

Dear Mr. Fatzinger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

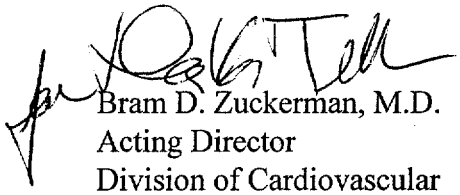
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
And Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Applicant: Hygia Health Services, Inc.

510(k) Number:

Device Name: Hygia Health Services Reprocessed Kendall SCD™ Sleeves

Indications For Use:

The Hygia Health Services Reprocessed Kendall SCD™ Sleeve is used in the treatment of venous leg ulcers and edema which are disorders associated with venous insufficiency.

The Hygia Health Services Reprocessed Kendall SCD™ Sleeve is also a non-invasive therapeutic method for prevention of deep vein thrombosis.

Suggested Use

When treating leg edema, sleeves may be used while the patient is in a sitting or supine position for 30 minutes to 2 hours, once or twice daily. The sleeves should only be used while the patient is awake. Treatment should be continued until swelling is at an acceptable level as determined by a physician.

When treating venous leg ulcers, sleeves may be used while the patient is in a sitting or supine position for 2 to 4 hours daily. Treatments should be conducted on patients while they are awake.

The frequency and duration of treatment periods may vary according to a physician's recommendation or the progress of the patient in response to compression therapy.

To prevent deep vein thrombosis, compression should be used constantly during times in which the patient is stationary.

Precautions and Contraindications

Contraindications:

Sleeves may not be recommended for the patients with the following:

1. Any local leg condition in which sleeves would interfere such as dermatitis, vein ligation (immediate postoperative), gangrene, or recent skin graft.

2. Severe arteriosclerosis or other ischemic vascular disease

3. Massive edema of legs or pulmonary edema from congestive heart failure

4. Extreme deformity of leg

5. Suspected existing deep venous thrombosis

Precautions:

1. One must assure that the device is properly applied and correctly connected to the air controller.

2. If the patient experiences numbness, tingling, or leg pain, the sleeves should be removed.

Caution:

This device is not intended for use in the Operating Room or in the presence of flammable anesthetics.

Division of Cardiovascular & Respiratory Devices
510(k) Number K012417

Prescription Use X
(Per 21 CFR 801.109)